



DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS



15 MAR 2017

MEMORANDUM FOR SGVT
ATTN: MAJ CARRIE LITKE-WAGER

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled **A Randomized Trial to Measure the Efficacy of Applying Task-Oriented Role Assignment to Improve Neonatal Resuscitation** presented at/published to **International Meeting on Simulation Healthcare, Orlando, FL, 28 January – 1 February 2016** in accordance with MDWI 41-108, has been approved and assigned local file #**17052**.
2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.
3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are a 59 MDW staff member, we can forward your request for funds to the designated Wing POC at the Chief Scientist's Office, Ms. Alice Houy, office phone: 210-292-8029; email address: alice.houy.civ@mail.mil.
4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

Linda Steel-Goodwin

LINDA STEEL-GOODWIN, Col, USAF, BSC
Director, Clinical Investigations & Research Support

| PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS | | | |
|---|---|---|---|
| 1. TO: CLINICAL RESEARCH | 2. FROM: (Author's Name, Rank, Grade, Office Symbol) Litke-Wager, Carrie, Major, O-4, SGVT | 3. GME/GHSE STUDENT: 181 YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> | 4. PROTOCOL NUMBER: C 2015.099d |
| 5. PROTOCOL TITLE: (NOTE: For each new release of medical research or technical information as a publication/presentation, a new 59 MOW Form 3039 must be submitted for review and approval.) A Randomized Trial to Measure the Efficacy of Applying Task-Oriented Role Assignment to Improve Neonatal Resuscitation | | | |
| 6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED: A Randomized Trial to Measure the Efficacy of Applying Task-Oriented Role Assignment to Improve Neonatal Resuscitation | | | |
| 7. FUNDING RECEIVED FOR THIS STUDY? <input type="radio"/> YES 181 NO <input checked="" type="radio"/> FUNDING SOURCE: | | | |
| 8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES: 181 YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> | | | |
| 9. IS THIS MATERIAL CLASSIFIED? <input type="radio"/> YES 181 NO <input checked="" type="radio"/> | | | |
| 10. IS THIS MATERIAL SUBJECT TO ANY LEGAL RESTRICTIONS FOR PUBLICATION OR PRESENTATION THROUGH A COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA), MATERIAL TRANSFER AGREEMENT (MTA), INTELLECTUAL PROPERTY RIGHTS AGREEMENT ETC.? <input type="checkbox"/> YES 181 NO <input checked="" type="checkbox"/> NOTE: If the answer is YES then attach a copy of the Agreement to the Publications/Presentations Request Form. | | | |
| 11. MATERIAL IS FOR: 181 DOMESTIC RELEASE <input type="checkbox"/> FOREIGN RELEASE <input checked="" type="checkbox"/> CHECK APPROPRIATE BOX OR BOXES FOR APPROVAL WITH THIS REQUEST. ATTACH COPY OF MATERIAL TO BE PUBLISHED/PRESENTED. | | | |
| <input type="checkbox"/> 11a. PUBLICATION/JOURNAL (List intended publication/journal.) | | | |
| <input type="checkbox"/> 11b. PUBLISHED ABSTRACT (List intended journal.) | | | |
| 181 11c. POSTER (To be demonstrated at meeting: name of meeting, city, state, and date of meeting.) International Meeting on Simulation Healthcare, Orlando, FL, 28 Jan 2016-01 Feb 2016 | | | |
| <input type="checkbox"/> 11d. PLATFORM PRESENTATION (At civilian institutions: name of meeting, state, and date of meeting.) | | | |
| <input type="checkbox"/> 11e. OTHER (Describe: name of meeting, city, state, and date of meeting.) | | | |
| 12. HAVE YOUR ATTACHED RESEARCH/TECHNICAL MATERIALS BEEN PREVIOUSLY APPROVED TO BE PUBLISHED/PRESENTED? <input type="checkbox"/> YES 181 NO <input checked="" type="checkbox"/> ASSIGNED FILE # _____ DATE _____ | | | |
| 13. EXPECTED DATE WHEN YOU WILL NEED THE CRD TO SUBMIT YOUR CLEARED PRESENTATION/PUBLICATION TO DTIC NOTE: All publications/presentations are required to be placed in the Defense Technical Information Center (DTIC) DATE December 20, 2016 | | | |
| 14. 59 MOW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email) Litke-Wager, Carrie Ann, R., carrie.a.litke-wager.mil@mail.mil | | | 15. DUTY PHONE/PAGER NUMBER 210-916-7078 |
| 16. AUTHORSHIP AND CO-AUTHOR(S) List in the order they will appear in the manuscript. LAST NAME FIRST NAME AND M.I. GRADE/RANK SQUADRON/GROUP/OFFICE SYMBOL INSTITUTION (if not 59 MOW) | | | |
| a. Primary/Corresponding Author | | | |
| Litke-Wager, Carrie | O-4/Major | 959CSPS/59MDW/SGVT | |
| b. Mu, Thornton | O-5/LTC | MCHE-ZDP-N | SAMMC |
| c. Delaney, Heather | O-4/MAJ | MCHE-ZDP-N | SAMMC |
| d. | | | |
| e. | | | |
| 17. ISA 502 ISG/JAC ETHICS REVIEW REQUIRED (JER DOD 5500.07-R)? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO | | | |
| I CERTIFY ANY HUMAN OR ANIMAL RESEARCH RELATED STUDIES WERE APPROVED AND PERFORMED IN STRICT ACCORDANCE WITH 32 CFR 219, AFMAN 40-401.1P, AND 59 MDWI 41-108. I HAVE READ THE FINAL VERSION OF THE ATTACHED MATERIAL AND CERTIFY THAT IT IS AN ACCURATE MANUSCRIPT FOR PUBLICATION AND/OR PRESENTATION. | | | |
| 18. AUTHOR'S PRINTED NAME, RANK, GRADE Litke-Wager, Carrie Ann, Major, O-4 | | 19. AUTHOR'S SIGNATURE _____ | 20. DATE November 28, 2016 |
| 21. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE Mu, Thornton, LTC, Neonatology Program Director | | 22. APPROVING AUTHORITY'S SIGNATURE _____ | 23. DATE November 28, 2016 |

| PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS | | | |
|---|--------------------------------|---|----------------------------|
| 1st ENDORSEMENT (59 MDW/SGVU Use Only) | | | |
| TO: Clinical Research Division 59 MDW/CRD Contact 292-7141 for email instructions. | 24. DATE RECEIVED 1/30/2017 | 25. ASSIGNED PROCESSING REQUEST FILE NUMBER 17052 | |
| 26. DATE REVIEWED 3/10/2017 | | 27. DATE FORWARDED TO 502 ISG/JAC | |
| 28. AUTHOR CONTACTED FOR RECOMMENDED OR NECESSARY CHANGES: <input type="checkbox"/> NO <input type="checkbox"/> YES If yes, give date. _____ <input type="checkbox"/> N/A | | | |
| 29. COMMENTS <input type="checkbox"/> APPROVED <input type="checkbox"/> DISAPPROVED IRB approved abstract submitted well after presentation was give. Appropriate disclaimers included and IRB approval included. Approved | | | |
| 30. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER Kevin Kupferer/GS13/Hum Res Subj Prot Exp | | 31. REVIEWER SIGNATURE KUPFERER.KEVIN.R <small>Digitally signed by KUPFERER.KEVIN.R.1086667270 DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, email=KUPFERER.KEVIN.R.1086667270 Date: 2017.03.13 06:26:15 -05'00'</small> | 32. DATE 3/10/2017 |
| 2nd ENDORSEMENT (502 ISG/JAC Use Only) | | | |
| 33. DATE RECEIVED | | 34. DATE FORWARDED TO 59 MDW/PA .1086667270 | |
| 35. COMMENTS <input type="checkbox"/> APPROVED (In compliance with security and policy review directives.) <input type="checkbox"/> DISAPPROVED | | | |
| 36. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER | | 37. REVIEWER SIGNATURE | 38. DATE |
| 3rd ENDORSEMENT (59 MDW/PA Use Only) | | | |
| 39. DATE RECEIVED March 14, 2017 | | 40. DATE FORWARDED TO 59 MDW/SGVU March 15, 2017 | |
| 41. COMMENTS <input checked="" type="checkbox"/> APPROVED (In compliance with security and policy review directives.) <input type="checkbox"/> DISAPPROVED | | | |
| 42. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER Kevin Inuma, SSgt/E-5, 59 MDW Public Affairs | | 43. REVIEWER SIGNATURE INUMA.KEVIN.MITSUGU. 1296227613 <small>Digitally signed by INUMA.KEVIN.MITSUGU.1296227613 DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USAF, cn=INUMA.KEVIN.MITSUGU.1296227613 Date: 2017.03.15 07:48:58 -05'00'</small> | 44. DATE March 15, 2017 |
| 4th ENDORSEMENT (59 MDW/SGVU Use Only) | | | |
| 45. DATE RECEIVED | | 46. SENIOR AUTHOR NOTIFIED BY PHONE OF APPROVAL OR DISAPPROVAL <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> COULD NOT BE REACHED <input type="checkbox"/> LEFT MESSAGE | |
| 47. COMMENTS <input type="checkbox"/> APPROVED <input type="checkbox"/> DISAPPROVED | | | |
| 48. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER | | 49. REVIEWER SIGNATURE | 50. DATE |

Hypothesis/Research Question/Objective

Despite receiving standardized Neonatal Resuscitation Program (NRP) training, providers frequently fail to comply with NRP guidelines during neonatal resuscitation. The most common deviations include ineffective ventilation technique, difficulty completing intubation, and improper medication administration. In an effort to address these performance gaps we devised a teaching paradigm, called 'Task-Oriented Role Assignment', in which we have delegated a specific set of tasks to be performed within the traditional role assignments used during NRP. We hypothesize that this method will improve communication and task delegation within the resuscitation team, resulting in improved NRP performance.

Methods

Participants include health care providers completing NRP. A sample size of 72 is needed to detect an effect size of 0.8 standard deviations. Participants are randomized to either the control group, and receive NRP only, or the study group, and receive NRP with additional training on the use of 'Task-Oriented Role Assignment'. This paradigm consists of 5 roles: team leader, cardiac chief, airway chief, line/medication chief, and recorder, with each role given a subset of pre-determined tasks. We have incorporated the mnemonic, 'B CALMR', into a visual aid. Participants are then randomized into smaller groups to participate in standardized NRP simulations using a high-fidelity patient simulator. The scenarios are video recorded and then evaluated for task completion and team behaviors by two blinded investigators. Participants complete a demographic survey and pre- and post-course self-assessment questionnaires in which they rate their ability to perform various aspects of NRP.

Results

To date we have enrolled 24 subjects with 12 participants in each group. Demographics were statistically similar between the control and study groups with the exception that a statistically higher number of 'real-world' resuscitations were reported among the control group (median 4.7 vs. 1.2; $p=0.03$). The control group rated themselves statistically higher than the study group in most categories of the pre- (mean difference 0.75-0.91, $p=0.004-0.4$) and post-course (mean difference 0.76-1.09, $p=0.00007-0.004$) self-assessments. The post-course assessments for both groups showed statistically significant improvement in each category when compared to pre-course assessments. For the control group the mean difference in scores ranged between 1.17-1.5 ($p=0.000001-0.0004$), and in the study group the mean difference in scores ranged from 1-1.4 ($p=0.000009-0.0006$). The difference in score improvement between the two groups was not statistically significant.

Conclusion

Regardless of group assignment, participants perceived their ability to perform NRP to be greater after receiving any NRP education. The control group had higher self-assessment scores than the study group. The significance of this is unclear, and needs to be correlated with the NRP task and team behavior performance scores, which are pending at this time.

Disclaimer

The views expressed are those of the author(s)/presenter(s) and do not reflect the official views or policy of the Department of Defense or its Components.



REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
REGIONAL HEALTH COMMAND CENTRAL (PROVISIONAL)
4070 STANLEY ROAD, SUITE 121
JBSA FORT SAM HOUSTON, TEXAS 78234-2715

MCSR-CS

15 June 2016

MEMORANDUM FOR: Maj Carrie Litke-Wager, MD
FROM: Brooke Army Medical Center Institutional Review Board
PROJECT TITLE: A Randomized Trial to Measure the Efficacy of Applying
Task-Oriented Role Assignment to Improve Neonatal
Resuscitation
REFERENCE #: C.2015.099d
SUBMISSION TYPE: Continuing Review/Progress Report
ACTION: APPROVED
IRB APPROVAL DATE: 15 June 2016
EXPIRATION DATE: 16 June 2017
REVIEW TYPE: Expedited
PROJECT STATUS: Active, Open to Enrollment

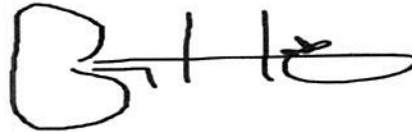
1. Congratulations! The Brooke Army Medical Center (BAMC) Institutional Review Board (IRB) reviewed and APPROVED continuation of your aforementioned protocol and supporting documents. The research continues to be judged Minimal Risk. Your protocol and continuing review application was reviewed for regulatory compliance under Expedited Review, in accordance with 32CFR219.110 (b)(1) Federal Register Categories 6 and 7. Applicable OHRP (under 45CFR46), FDA (under 21CFR50 and 56) and HIPAA (45CFR160 and 164) regulations were also consulted, as appropriate.

2. The following minor changes in research were also requested and approved in accordance with 32CFR§219.110(b)(2).

- P01 removed Dr Ward as statistician. Respective changes now reflected in P01 Version 2, 13 June 2016.

3. This protocol will automatically expire on June 16, 2017. If you plan to continue beyond this date, the required continuing review progress report is due to the BAMC IRB no later than six (6) weeks prior to expiration. Please Note: If a Data Safety and Monitoring Board (DSMB) has been named, please submit its most recent report with your annual Continuing Review. The IRB will attempt to assist you by sending a reminder; however, submission of the continuing review report is your responsibility. Failure to submit the report on time will result in the expiration of your protocol and a requirement to cease all research activities until the protocol can be reapproved.

4. If at any time you have questions regarding your responsibilities as a Principal Investigator, please do not hesitate to contact Amy Holstein at 210-916-8227 or amy.l.holstein.civ@mail.mil. On behalf of the entire IRB, we wish you much success with your research protocol. We look forward to reviewing the progress of your study in the coming months.

A handwritten signature in black ink, appearing to read 'A. Holstein', with a stylized flourish at the end.

AMY L. HOLSTEIN
RN, MPH, CCRP, CIP
Designated Expedited Review IRB Member